

**What You Always Wanted to Know About
Root Cause Analysis and Management
Review, but Were Afraid to Ask**

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**Critical ISO/IEC 17025:2005
Accreditation Requirements**

- ▶ Quality Manual
- ▶ Document Control
- ▶ Traceability
- ▶ Control of Non-conformances
- ▶ Root Cause Analysis
- ▶ Corrective Action
- ▶ Internal Audit
- ▶ Management Review

Root Cause Analysis

4.11.2 Cause analysis

- ▶ “The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.”

Do not skip this investigation!!!

The Challenges of Root Cause Analysis

▶ Note to 4.11.2

- ▶ “Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required.”

When is Root Cause Analysis Required?

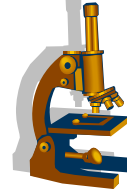
- ▶ A non-conformance has been identified through a variety of activities:
 - Internal audit findings cast doubt on the effectiveness of the operation
 - External audit findings cast doubt on the effectiveness of the operation
 - Complaints from customers
 - Management reviews

Identifying the Process Failure

- ▶ Do not decide the cause before the investigation
- ▶ Start a corrective action record
 - ▶ Finding: Concise and specific
- ▶ Something in the process must change to reduce the likelihood of recurrence

The Investigation

- ▶ What happened?
- ▶ Why did it happen?
- ▶ When did it happen?
- ▶ What else was happening during that timeframe?
- ▶ Where else do we look for more information?
- ▶ Has the problem occurred in the past?



Root Cause Analysis Tools

- ▶ An Iterative Process
- ▶ Five Whys
- ▶ Failure Mode and Effects Analysis
- ▶ Tree Diagrams
- ▶ Fishbone Diagram

The Specific Tool Chosen is not Important!!!

Immediate Fix

- ▶ Put Out the Fire!!
- ▶ Initial Corrective Action!!
- ▶ Do Not Stop Here!!

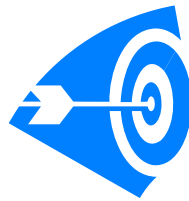


Corrective Action

- ▶ Avoid implementing all solutions at once
 - Many labs try everything!!
- ▶ Select the action that appears to be the one that will most likely solve the problem
- ▶ Monitor the Process

Prevent the Problem from Recurring

- ▶ Fix the problem, not just the symptom
- ▶ Avoid repeating the same mistakes
- ▶ The 100 Year Fix!!



Management Review

Definition

“Management review is a regular systematic evaluation by top management of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives .” (APLAC TC 003)

Who is chosen to participate?

- ▶ Head of the Organization
- ▶ Technical Management
- ▶ Quality Manager
- ▶ Section Heads
- ▶ In a small organization, one staff member might be responsible for more than one function

Required Agenda

- ▶ Suitability of Policies and Procedures
- ▶ Reports from Managerial and Supervisory Personnel
- ▶ Outcome of Recent Internal Audits
- ▶ Corrective and Preventive Actions
- ▶ Assessments by External Bodies
- ▶ Results from Participation in a Proficiency Testing Program

Required Agenda (cont'd)

- ▶ Changes in Volume and Type of Work
- ▶ Customer Feedback
- ▶ Complaints
- ▶ Recommendations for Improvement
- ▶ Other Relevant Factors (quality control activities, resources, staff training)

Scheduling Management Review

- ▶ Pre-determined schedule
- ▶ Complete management review prior to accreditation
 - Sometimes an issue with new laboratories seeking accreditation

Preparing for a Management Review Meeting

- ▶ Formal Agenda
- ▶ Assemble control charts, proficiency testing results, internal audit reports, customer feedback, and complaints
- ▶ Future plans and estimates of new work

Conducting a Management Review Meeting

- ▶ Head of organization chairs the meeting
- ▶ Follow agenda so all elements included
- ▶ Meet the needs of the organization and its customers

Outcomes

- ▶ Action Plan
 - Fix Problems
 - Set Goals
 - Identify resources
- ▶ A Person Responsible for Each Action
- ▶ Deadlines Are Set
- ▶ Results are Monitored

More Information

- ▶ www.aoac.org
- ▶ Inside Laboratory Management
 - 2006: How to Perform Root Cause Analysis by Dawn Mettler
 - 2010 May/June: Resources for Root Cause Analysis by Bill Mills
 - 2010 July/ August: How Management Review Can benefit the Laboratory by Arlene Fox

TDLM Workshop at AOAC Annual Meeting

- ▶ Why did that Happen? How do I Fix It? Root Cause Analysis and CAPA as Told by Those Who Live It Every Day in the Lab
 - Chair: Michele Smoot
 - Cathy L. Burns: The Corrective Action Process
 - Kenneth P. Stoub: Root cause Analysis and Corrective Actions

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Questions?

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